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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TOSCANO, ALICIA

ART UNIT

PAPER NUMBER

1796

MAIL DATE

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11/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,061	Applicant(s) COSZACH ET AL.	
	Examiner Alicia M. Toscano	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-14,21-26,36,37 and 39-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-14,21-26,36,37 and 39-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 10, 26, 48-52 are objected to because of the following informalities:
Claims 1 and 3, to which the above depend from, require a meso-lactide content of less than 1% in step (d). The above claims have the limitation "and a meso-lactide content of between 0 and 15%". It is unclear to the Examiner how the m-lactide content can be above 1% when the claim 1 is limited to being less than 1%. Appropriate correction/clarification is required.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 3, 5, 6, 9, 10, 21, 22, 25, 26, 44, 45, 48, 49 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi (US 5502215) in view of O'Brien (US 6310218).

Yamaguchi discloses methods for the purification of lactide. Column 1 lines 47-60 disclose the process elements (a)-(c), using lactic acid, of Applicant's claim 1, wherein process step (a) is carried out to obtain a MW of lactic prepolymer of 400-3000 (Column 4 line 49). As the process requirements and resulting MW required of (a) are met, the Examiner finds the other properties of (a) to be inherent in the composition. Extractive crystallization wherein water is added to the crude lactide and crystals are formed is disclosed in Column 3 lines 36-56. Applicant's Examples disclose cooling the

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aqueous solution to the crystallization temperature and holding for 30 minutes to promote nucleation and growth, resulting in the controlled geometry required by (e1) of claim 1. Yamaguchi discloses holding the water/lactide mixture at a temperature around 30C for 30 mins to 1 hr (Column 6 lines 60-Column 7 line 9), which overlaps the process of Applicants and thusly must result in the desired controlled geometry of Claim 1. The resulting crystals are filtered and further dried (Column 11 line 19), meeting all the requirements of (e) of Claim 1. Melt crystallizing the crude lactide product prior to the aqueous extraction is disclosed in Column 6 lines 60-65 and Ex 2, Column 11 lines 8-10. Thusly, the process steps of (a)-(e) are all met.

Yamaguchi includes the process steps set forth above, but Yamaguchi does not disclose using melt crystallization in order to provide a m-lactide content of less than 1%, as further required by (d). Specifically, Ex 2 discloses that the melt crystallization /aqueous extraction results in a m-lactide content of 2.2 wt%.

O'Brien discloses melt crystallization purification of lactides. O'Brien discloses that the process of melt crystallization can be varied in order to achieve maximum purity by adjusting the rate of cooling during crystallization (Column 3 lines 51-56). O'Brien thusly teaches the rate of cooling and the amount of impurities to be a result effective variable.

It would have been obvious to one of ordinary skill in the art at the time of the invention to vary the rate of cooling during crystallization in Yamaguchi, as taught by O'Brien, in order to achieve a lactide product with the desired m-lactide residue.

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Thusly, O'Brien and Yamaguchi meet all the limitations of Claim 1. The purified lactide monomers are used to make polylactic acid (Column 1 lines 19-21), as required by Claim 3. Claims 5, 6, 21 and 22 are drawn to an optional element and are thusly rejected. As the compositional and process elements are met the Examiner finds the properties of Claims 9, 10, 25, 26, 44, 45, 48, 49 and 52 to be inherent.

3. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi and O'Brien '218 in further view of O'Brien (US 5521278)

Yamaguchi and O'Brien '218 include elements as set forth above. Yamaguchi and O'Brien do not disclose the specific polymerization steps of the final polylactide product.

O'Brien discloses the manufacture and polymerization of lactide. The polymerization steps include addition of a catalyst to the lactide (Column 9 line 64-Column 10 Line 19), which will inherently form a mixture since one would blend the catalyst and lactide to form a uniform mixture prior to polymerization in order for the reaction to have high yield, and then further polymerizing in an extruder (Column 10 Lines 40-41). The initiation step (b) requires initiation via addition of optional comonomers and the like. Since the addition of said monomers is optional, step (b) does not necessitate any further steps other than the addition of a catalyst and the polymerization in an extruder, as discussed above. Said method results in high polymer yield and low polymerization time (Column 10 Lines 20-23).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include in Yamaguchi and O'Brien '218 the use of a polymerization catalyst and extruder, as taught by O'Brien, in order to reduce the polymerization time whilst obtaining high polymer conversion. Thusly, the limitations of Claims 11 and 12 are met.

1. Claims 7, 8, 13, 14, 23, 24, 36, 37, 39-43, 46, 47, 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi and O'Brien '218 in further view of Gruber (US 6326458).

Yamaguchi and O'Brien '218 include elements as set forth above. Yamaguchi and O'Brien do not disclose recycling the product streams during production.

Gruber discloses the continuous process for manufacturing lactide polymers. Said process includes recycling distilled, impurity containing fractions back to the reactor itself or other upstream process equipment (Column 7 lines 64-Column 8 line 14) so that there is no waste of the raw material lactic acid feed.

It would have been obvious to one of ordinary skill in the art at the time of the invention to include in Yamaguchi and O'Brien the use of recycling the impurity fractions back into the process feeds, as taught by Gruber, in order to minimize the waste of raw material. The recycling step meets the limitations of the above claims.

Conclusion

Response to Arguments

2. Applicant's arguments filed 9/26/07 have been fully considered but they are not persuasive. Examiner believes Applicant's argument to be that Gruber discloses the opposite process steps, namely, that Gruber reverses (d) and (e) of Claim 1 and that if Van Gansberghe was employed in the process of Gruber, the process would have completely different results. The Examiner is confused, since Gruber was used to teach process steps (a)-(c) and Van Gansberghe was used to teach (d) and (e), and thusly the Examiner finds Applicant's arguments unpersuasive.

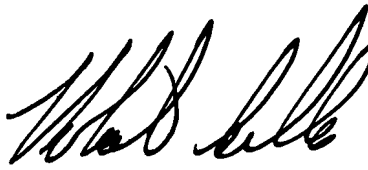
3. Claim 1 requires melt crystallization followed by extractive crystallization. Van Gansberghe teaches extractive crystallization followed by melt crystallization. The Examiner had previously rejected Claim 1 over Example 2 of Van Gansberghe, however after further consideration the Examiner finds that the reversed steps of melt crystallization followed by extractive crystallization are not met by Van Gansberghe. Further, Van Gansberghe teaches that the steps of extractive crystallization followed by melt crystallization, in that order, are critical to the invention. Thusly the previous rejection of Claim 1 in view of Van Gansberghe and its dependants is withdrawn. New grounds of rejection are set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia M. Toscano whose telephone number is 571-272-2451. The examiner can normally be reached on Monday to Friday 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on 571-272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMT



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